

REMARKS

In the Examiner's Final Office Action, the Examiner rejected claims 1, 3-5 and 7 pending in the application. In response to the Examiner's Office Action, Claims 5 and 7 have been cancelled without disclaimer or prejudice. Claims 1 and 3-4 remain pending in the application. Reconsideration is respectfully requested.

The Examiner first rejected claims 5 and 7 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In that Applicants have cancelled claims 5 and 7, without disclaimer or prejudice, the Examiner's rejection is now moot.

Claims 1, 3 and 4 stand rejected under 35 U.S.C. §102(a) as being anticipated by Bieber et al. More specifically, the Examiner contends that Bieber discloses a filter pipette tip having an affinity reagent (beads containing immobilized antibodies) present within the tip. In responding to the Examiner's prior office action regarding the Bieber reference, Applicants argued that Bieber did not constitute a description of the invention in a printed publication before the invention was made by Applicants because Applicants are the authors of the journal article and Applicants conceived their invention before the publication of the Bieber reference. In responding to Applicants' argument, the Examiner stated that he did not find Applicants' argument persuasive because they had not submitted a declaration that demonstrates that Allan L. Bieber did not take part in the conception of the subject matter disclosed and claimed in the instant patent application, and also failed to disclose the work that was performed by Allan L. Bieber in connection with the Bieber reference.

In response to the Examiner's remarks regarding the Bieber reference, Applicants have submitted herewith a declaration signed by Randall W. Nelson, an inventor in the instant application and the principal investigator involved in the printed publication entitled "Mass Spectrometric Immunoassay", Anal. Chem. 1995, 67. 1153-1158. listing Randall W. Nelson, Jennifer R. Krone, Allan L. Bieber, and Peter Williams as authors. Mr. Nelson's declaration states that the work performed by Mr. Allan L. Bieber in connection with the instant reference comprised conducting experiments related to the invention under Mr. Nelson's direction. Mr.

Nelson's declaration also states that Mr. Allan L. Bieber did not take part in the conception of the subject matter disclosed and claimed in the instant patent application. Accordingly, Applicants conceived of their invention before the publication of the journal article cited by the Examiner because they were the authors of that journal article. As a result, the journal article cited by the Examiner does not constitute a description of the invention in a printed publication before the invention was made by Applicants. Applicants respectfully request the withdrawal of the Examiner's 35 U.S.C. §102(a) rejection based on Bieber.

Claim 1 stands rejected under 35 U.S.C. §102(e) as being anticipated by Ollington et al, U.S. Patent No. 5,403,745, issued April 4, 1995 (hereinafter "Ollington"). More specifically, the Examiner states that Ollington discloses a pipette comprising antibodies immobilized to beads and that Ollington also discloses a pipette tip having a filter. Applicants respectfully traverse this rejection.

Ollington generally discloses a method for determining an analyte in a biological fluid sample in the presence of a substance interfering with an assay for the analyte. More specifically, Ollington discloses a reaction pipette 114 and a docking assembly 116 (see FIG. 12). The docking assembly includes a filter 118 at its bottom. The reaction pipette 114 contains prepacked aliquots of antibodies immobilized, for example, on beads or a coiled strip (FIG. 13), or otherwise in the manner as discussed above in connection with FIG. 8." (See column 13, lines 24-27). It is clear that the filter material is positioned within the docking assembly and not within the pipette (see column 13, lines 51-54). Therefore, Ollington fails to disclose each and every element of Applicants' claimed invention, namely at least an antibody or antigen immobilized to a solid substrate to form an affinity reagent and a pipette tip having a filter element contained therein for retaining the affinity reagent. In Ollington, the filter element is clearly not contained within the pipette tip. Therefore, Applicants respectfully request the withdrawal of the Examiner's 35 U.S.C. §102(e) rejection based on Ollington.

Claims 1 and 3-5 also stand rejected under 35 U.S.C. §102(e) as being anticipated by Wainwright et al., WO 94/20831 (hereinafter "Wainwright"). In particular, the Examiner states that Wainwright et al. discloses a micropipette tip having a porous element and fiber layers retained on top of the porous element. The Examiner further states that Wainwright discloses

that antibodies are immobilized on these fiber layers and that the porous element is securely fixed to the tip. Applicants respectfully traverse this rejection.

Wainwright generally discloses a pre-activated chromatography tip having covalent coupling functionality within a hydrodynamically designed micropipette tip. The pre-activated micro-channeled element provides high fluid directionality and throughput with minimum back pressure. In particular, a conical receptor element 20 is contained within a pipette tip. This reactive element 20 is made from a porous material, preferably non-biaxially oriented fibers made from cellulose acetate or the like, and are arranged so as to be continuous from one end of the element to the other. (See page 5, paragraph 2). However, the pipette tip may also contain a modified receptor element 30 which constitutes a multi-layered receptor element. In this embodiment, element 30 comprises a first layer 31 positioned adjacent the smaller end of the tip 21, a second layer 32 which is seated against the end of a layer 31 remote from the small end of the tip, and a third layer 33, which engages layer 32 to sandwich the latter between layers 31 and 33. Each of the layers 31 through 33, of course, is made from a porous material such as for example the fibrous material noted above in connection with the receptor element 20. (See page 9, full paragraph 1, and FIG. 3). Unlike Applicants' claimed invention, Wainwright fails to disclose at least one antibody or antigen immobilized to a solid substrate to form an affinity reagent which is then retained within a filter element contained within a pipette tip. Accordingly, Wainwright fails to disclose each and every element of Applicants' claimed invention and therefore cannot anticipate Applicants' claimed invention. Applicants respectfully request the Examiner's withdrawal of his 35 U.S.C. §102(e) rejection based on Wainwright.

Finally claim 7 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Bieber et al. in view of Raybuck et al. Although Applicants contend that Bieber et al. does not constitute a prior art reference with respect to Applicants' pending application, this rejection is now considered moot in that Applicants have cancelled claim 7 without disclaimer or prejudice.

In view of the foregoing, Applicant respectfully submits that all of the pending claims fully comply with 35 U.S.C. §112 and are allowable over the prior art of record. Reconsideration of the application and allowance of all pending claims is earnestly solicited. Should the Examiner wish to discuss any of the above in greater detail or deem that further

amendments should be made to improve the form of the claims, then the Examiner is invited to telephone the undersigned at the Examiner's convenience.

Respectfully submitted,

By:   
Laura J. Zeman  
Reg. No. 36,078

**SNELL & WILMER L.L.P.**  
One Arizona Center  
400 East Van Buren  
Phoenix, Arizona 85004-2202  
Telephone: (602) 382-6377  
Facsimile: (602) 382-6070